

REMARKS

This Response is made to the Office Action dated January 8, 2008. Claims 2, 4, 6-9, 13 and 15-19 are pending in this application. Applicants respectfully request reconsideration of the claims in view of the remarks presented below.

Claims 13, 15 and 18 were rejected under 35 U.S.C. § 103(a) as being unpatentable over WO99/49808 to Gilson et al. (the "Gilson reference") in view of U.S. Patent No. 5,501,654 to Failla et al. (the "Failla patent"). The Examiner has taken the position that the device disclosed in the Gilson reference can be combined with certain elements from the device disclosed in the Failla patent to create Applicants' currently pending invention. However, Applicants strongly disagree with the Examiner's position. The device in the Gilson reference requires the use of a specialized retraction mechanism, which requires the use of a threaded rod 40 and thumbwheel to retract the outer sheath proximally from the collapsed stent. The Gilson reference, as the Examiner correctly notes, lacks a thumbwheel that rotates about an axis of rotation which is substantially perpendicular to the linear movement of the retraction mechanism. The Gilson device, however, lacks much more including the particular retraction mechanism recited in the claims, along with the stop means and means for allowing motion of the gear rack in only one direction. As will be discussed below, the device disclosed in the Failla patent also fails to disclose these particular structure as well.

The actuating mechanisms disclosed in the Gilson reference and the Failla patent would not be readably interchangeable as suggested by the Examiner. Claim 13 requires the proximal end of the inner catheter member to be attached to the control handle and the proximal end of the outer restraining member to be attached to the retraction mechanism. In the Gilson device, the outer sheath 20 (the "outer restraining member") is retracted by the actuating mechanism to uncover the collapsed stent. As pointed out in Applicants' previously filed

Amendment, the actuating mechanism in the Failla patent does not move an outer sheath **14** since the outer sheath **14** is affixed to the handle **12**. In the Failla patent, the actuating mechanism actually moves an elongated element **16** located within the sheath **14** in order to allow a curved working section **22** to move outwards out of the sheath. In the Gilson device, the outer sheath **20** is retracted in order to uncover a collapsed stent. Therefore, there is an obvious incongruity in combining these patents together as suggested by the Examiner due to the different movement, and non-movement, of elements achieved by each of the disclosed retraction mechanisms. The Examiner's position that these mechanisms can be simply interchanged requires one to disregard the relationship between moving and stationary components making up the various devices. For these reasons alone, the combination of the Gilson reference with the Failla patent fails to achieve the particular structure recited in the pending claims.

The Examiner's position regarding the structure of the device disclosed in the Failla patent is also incorrect for several reasons. First, claim 13 requires a retraction mechanism that includes a gear rack which is slidable within a channel formed in the control handle and a **spur gear** which engages the gears of the gear rack. The retraction mechanism further requires a thumbwheel having an **actuating gear** attached thereto which engages the spur gear to cause the gear rack to move linearly within the channel when the thumbwheel is rotated. In the Failla device, a **single** pinion gear **48** connected to the thumbwheel **50** is disclosed and is used to engage the gear rack **44**. Clearly, there is a lack of a second gear used to engage the gear rack **44**. Therefore, the Failla device lacks specific components recited in the present claims.

The Examiner has further taken the position that the plastic strip **58** in the Failla device can be simply moved to contact the gear rack **44**. The location of the plastic strip **58** against the notches of the thumbwheel **50** in the Failla device,

however, is somewhat critical since the Failla patent discloses that there can be either distal or proximal movement of the gear rack **44**. Distal movement is needed to move the elongated member **16** and the working section **22** outside of the sheath **14** for deployment. Proximal motion of the gear rack **44** would be needed to retract the extended elongated member **16** back into the sheath **14** once the device is to be withdrawn from the patient. If the plastic strip **58** is placed against the gear rack, as suggested by the Examiner, the elongate member **16** would not be capable of being retractable back within the sheath **14** after deployment. This arrangement would thwart the user's ability to effectively use the surgical instrument disclosed in the Failla patent. Accordingly, one skilled in the art would not want to place the plastic strip **58** against the gear rack **44** since it would prevent the actuating mechanism from moving the gear rack **44** and elongated member **16** both distally and proximally as is needed to utilize the device. Moreover, there would be no need for one skilled in the art to even consider placing the plastic strip **58** against the gear rack **44** since the plastic strip **58** works effectively when placed against the thumbwheel **50**. Applicants believe that the Examiner is overreaching with her interpretation of the Failla patent in an attempt to achieve the structure of the pending claims.

The Examiner also claims that the stop pin **59** in the Failla device constitutes the means for preventing unintentional movement of the gear rack recited in claim 13. However, this stop pin **59** merely prevents the gear rack **44** of the Failla device from moving any further in a proximal direction. This stop pin **59** does not prevent movement of the gear rack in a distal direction. Therefore, this stop pin **59** does not function as a means for preventing unintentional movement (in any direction) of the gear rack, as stated by the Examiner.

Applicants submit that the Examiner has used impermissible hindsight to attempt to reconstruct Applicants' currently claimed invention. In this regard, the

Examiner has used the claims as a road map to selectively pick and chose elements appearing in the prior art in an attempt to create the claimed structure. However, even in doing so, the Examiner has failed to establish a *prima facie* case of obviousness. The actuating mechanisms disclosed in the Gilson reference and the Failla patent are completely different. One skilled in the art would simply not interchange one for the other. However, even assuming *arguendo* that the mechanisms could be interchanged as suggested by the Examiner, the mechanism of the Failla patent requires the sheath 14 (the "outer retraining member") to be rigidly attached to the handle with the inner member being movable outside of the sheath 14 by the actuating mechanism. This is clearly not the composition of elements recited in the pending claims. Moreover, certain components of the particular retraction mechanism recited in the claims are not found in either the Gilson reference or the Failla patent. Further, one skilled in the art would not move the plastic strip 58 to contact the gear rack 44, as suggested by the Examiner, since the plastic strip 58 works effectively when position against the thumbwheel 50. The stop means is also lacking in both the Gilson reference and the Failla patent. Accordingly, for at least the numerous reasons stated above, the combination of the Gilson reference with the Failla patent fails to achieve the basic structure recited in the pending claims. Applicants respectfully request the Examiner to withdraw all of the obviousness rejections.

Claims 2, 6, 16 and 19 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Gilson reference in view of the Failla patent and in further of U. S. Patent no. 6,146,415 to Fitz (the "Fitz patent"). As addressed above, the combination of the Gilson reference with the Failla patent fails to achieve the basic structure of the device recited in claim 13. The Fitz patent does not provide any teachings which bear on the failure of the Gilson/Failla combination to achieve the basic structure recited in these claims. For at least this reason, the

combination of the Gilson reference with the Failla and Fitz patents fails to achieve the structure recited in these claims. Applicants respectfully request that the rejection of these claims under 35 U.S.C. 103(a) be withdrawn.

Claim 4 was rejected under 35 U.S.C. 103(a) as being unpatentable over the Gilson reference in view of the Failla as applied to claim 13 and in further view of U.S. Patent No. 6,860,898 to Stack et al. (the "Stack patent"). Again, as addressed above, the combination of the Gilson reference with the Failla patent fails to achieve the basic structure recited in claim 13. For this reason alone, claim 4 is patentably distinct from the cited art. Applicants note that the Stack patent fails to disclose the various elements lacking in the combination of the Gilson and Failla devices. Therefore, the combination of the Stack patent with these other patents fails to achieve the structure recited in claim 4. Applicants again respectfully request that the rejection under 35 U.S.C. 103(a) be withdrawn.

Claims 7 and 17 were rejected under 35 U.S.C. 103(a) as being unpatentable over the Sullivan patent in view of the Failla and Fitz patents as applied to claim 19 and in further view of U.S. Patent No. 6,183,443 to Kratoska et al (the "Kratoska patent"). As addressed above, the combination of the Gilson reference with the Failla patent fails to achieve the basic structure of the device recited in claim 13. Neither the Fitz patent nor the Kratoska patent provides any teachings or disclose the missing elements of the Gilson/Failla combination. Accordingly, for at least this reason, the combination of the Gilson reference with the Failla, Fitz and Kratoska patents fails to achieve the structure recited in these claims. Applicants respectfully request that the rejection of these claims under 35 U.S.C. 103(a) be withdrawn.

Claims 8 and 9 were rejected under 35 U.S.C. 103(a) as being unpatentable over the Gilson reference in view of the Failla in view of the Fitz patent in view of the Kratoska patent as applied to claim 7 and in further view of U.S. Patent No. 4,624,243 to Lowery et al. (the "Lowery patent"). Again, the

combination of the Gilson reference with the Failla patent fails to achieve the basic structure of the device recited in claim 13. Neither the Fitz, Kratoska or the Lowery patents disclose the claimed elements which are missing from claim 13. Accordingly, for at least this reason, the combination of the Gilson reference with the Failla, Fitz, Kratoska and Lowery patents fails to achieve the structure recited in these claims. Applicants respectfully request that the rejection of these claims under 35 U.S.C. 103(a) be withdrawn

It is respectfully urged that all of the present claims of the application are patentable and in a condition for allowance. The undersigned attorney can be reached at (310) 824-5555 to facilitate prosecution of this application, if necessary.

In light of the above amendments and remarks, Applicants respectfully request that a timely Notice of Allowance be issued in this case.

Please charge any fees payable in connection with this response to Deposit Account No. 06-2425.

Respectfully submitted,

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